CHAPTER 4 (C)

Health certificate

For blood products to be used for technical purposes, including pharmaceuticals, in vitro diagnosis and laboratory reagents, but excluding serum of equidae, intended for dispatch to the European Community

Note for the importer: This certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

1. **Consignor** (name and address in full)
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2. **Consignee** (name and address in full)
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5. **Destination of the blood products**
5.1. EU Member State: .....
5.2. Name and address of the destination: .....
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.....
.....

7. **Means of transport and consignment identification** (2)
7.1. (Lorry, rail wagon, ship, or aircraft) (3)
7.2. Number of seal (if applicable): .....
7.3. Registration number(s), ship name or flight number: .
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.....

VETERINARY CERTIFICATE
For blood products to be used for technical purposes, including pharmaceuticals, in vitro diagnosis and laboratory reagents, but excluding serum of equidae, intended for dispatch to the European Community

Reference number (1) ORIGINAL

3. **Origin of the blood products**
3.1. Country: .....
3.2. Code of territory: .....

4. **Competent Authority**
4.1. Responsible Ministry: .....
4.2. Certifying department: .....
.....

6. **Place of loading for exportation**
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.....
.....

7.4. Nature of packaging: .....
.....
7.5. Number of packages: .....
7.6. Net weight: .....
7.7. Lot/batch production reference number:
.....
.....

8. **Identification of the blood products**
8.1. Nature of the blood products: .....
8.2. Species of animals from which the blood products derive: .....
.....
8.3. Address and registration number of the approved establishment: .....
.....

9. **Health attestation**

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1774/2002 (4) and certify that the blood products described above:

9.1. consist of blood products that satisfy the health requirements below;

9.2. consist exclusively of blood products not intended for human or animal consumption;

9.3. have been prepared exclusively with the following animal by-products:

(3) *either* [- blood of slaughtered animals, which is fit for human consumption in accordance with Community legislation, but is not intended for human consumption for commercial reasons;]

(3) *and/or* [- blood of slaughtered animals, which is rejected as unfit for human consumption but is not affected by any signs of diseases communicable to humans or animals, derived from carcasses that are fit for human consumption in accordance with Community legislation;]

(3) *and/or* [- blood obtained from animals other than ruminants that are slaughtered in a slaughterhouse, after undergoing ante mortem inspection, and were fit, as a result of such inspection, for slaughter for human consumption in accordance with Community legislation;]

(3) *and/or* [- blood and blood products derived from the production of products intended for human consumption;]

(3) *and/or* [- blood and blood products originating from animals that did not show clinical signs of any disease communicable through that product to humans or animals;]

(3) *either* [9.4. in the case of blood products derived from ruminant animals they originate in a third country or regions where:

(3) *either* [the animals and products come from a region where no case of foot-and-mouth disease, vesicular stomatitis, rinderpest, peste des petits ruminants, Rift Valley fever and bluetongue (5) has been recorded for 12 months and in which vaccination has not been carried out against those diseases for at least 12 months and from which imports of ruminant animals are authorised pursuant to Community legislation. The blood from which such products are manufactured must have been collected:

(3) *either* [in slaughterhouses approved in accordance with Community legislation,]

(3) *or* [from live animals in facilities approved in accordance with Community legislation,]

(3) *or* [in slaughterhouses approved and supervised by the competent authority of the third country. In this case the Commission and Member States must be notified of the address and approval number of such slaughterhouse and the certificate shall indicate this information,]]

(3) *or* [the products have undergone one of the following treatments, guaranteeing the absence of pathogens of the ruminant diseases foot-and-mouth disease, vesicular stomatitis, rinderpest, peste des petits ruminants, Rift Valley fever and bluetongue (5):

(3) *either* [heat treatment at a temperature of 65 °C for at least three hours, followed by an effectiveness check,]

(3) *or* [irradiation at 2,5 megarads or by gamma rays, followed by an effectiveness check,]

(3) *or* [change in pH to pH 5 for two hours, followed by an effectiveness check,]

(3) *or* [heat treatment of at least 90 °C throughout their substance, followed by an effectiveness check,]]

(3) *or* [sero-positive bluetongue animals are present, and the blood and blood products are intended for technical purposes including pharmaceuticals, in vitro diagnosis and laboratory reagents, to be processed in the approved plants [approval number] in [Member State] (6)]]

(3) *or* [9.4. in the case of blood products derived from animals excluding ruminants they originate in a third country or regions where:

(3) *either* [the animals and the products come from a region where no case of foot-and-mouth disease, swine vesicular disease, classical swine fever, African swine fever, Newcastle disease or avian influenza has been recorded for 12 months in the susceptible species and in which vaccination has not been carried out against those diseases for at least 12 months. The health certificate shall follow the model according to the species of animal from which the blood products are derived;]

(3) *or* [the products have undergone a heat treatment at a temperature of 65 °C for at least three hours, followed by an effectiveness check, guaranteeing the absence of pathogens of the following diseases:

foot-and-mouth disease, swine vesicular disease, classical swine fever, African swine fever, Newcastle disease or avian influenza in the susceptible species;]]

9.5. the end product was:

(3) *either* [packed in new or sterilised bags,]

(3) *or* [transported in bulk in containers or other means of transport that were thoroughly cleaned and disinfected with a disinfectant approved by the competent authority before use,]

and which bear labels indicating 'NOT FOR HUMAN OR ANIMAL CONSUMPTION';

9.6. the end product was stored in enclosed storage;

9.7. the product has undergone all precautions to avoid contamination with pathogenic agents after treatment.

Official stamp and signature

Done at ..... on .....
(place) (date)

.....
(stamp) (7) (signature of the official veterinarian) (7)

.....
(name, qualifications and title, in capital letters)

Notes

(1) Issued by the competent authority.
(2) For goods vehicles the registration number should be given. For bulk containers, the container number and the seal number (if applicable) should be included.
(3) Delete as appropriate.
(4) OJ L 273, 10.10.2002, p. 1.
(5) In the case of countries in which bluetongue sero-positive ruminant animals are present, blood products have been treated or the animals have been tested seronegative.
(6) This must be the same Member State of first entry of the products into the Community.
(7) The signature and the stamp must be in a different colour to that of the printing.